CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-600

MICROBIOLOGY REVIEW(S)

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CONSULTATIVE REVIEW TO HFD-540 DIVISION OF MEDICAL IMAGING, SURGICAL, and DENTAL DRUG PRODUCTS; HFD-160 MICROBIOLOGIST'S REVIEW OF NDA

AUG 9 1999

August 9, 1995

A. 1. NDA 20-600

APPLICANT:

Allergan, Inc.

P.O. Box 19534 2525 Dupont Drive

Irvine, CA 92713-9534 USA

2. PRODUCT NAMES:

Tazarotene

AGN 190168

Ethyl 6-[(4,4-dimethylthiochroman-6-

yl)ethyl]nicotinate

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

Topical Gel. It is packaged in collapsible aluminum tubes, in 10 gram, 30 gram, and 100 gram sizes containing either 01% or 0.05% Tazarotene gel.

4. METHODS OF STERILIZATION:

None. The drug product is a gel preserved with 1.0% (w/w) benzyl alcohol.

5. PHARMACOLOGICAL CATEGORY:

For the topical treatment of plaque psoriasis and the topical treatment of acne.

B. 1. DATE OF INITIAL SUBMISSION:

June 16, 1995

2. RELATED DOCUMENTS:

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DMF

DMF

DMF

DMF

3. AMENDMENT DATE: June 28, 1995. This amendment to the pending NDA submission was submitted as information for the microbiology review.

CC:

- 4. ASSIGNED FOR REVIEW: July 5, 1995
- C. REMARKS: The NDA 20-600 provides for Tazarotene, a non-sterile and preserved topical gel formulation, for use in cases of plaque psoriasis and acne. An amendment to the original NDA submission was provided by the sponsor for the microbiology review. This amendment contains information also found in the original submission.
- **D. CONCLUSIONS:** The NDA 20-600 for Tazarotene is approvable pending resolution of certain microbiology issues.

Patricia F. Hughes, Ph.D. Review Microbiologist

Original NDA 20-600 HFD-160/Consult File HFD-160/P.F.Hughes/8/9/95 HFD-540/Division File HFD-540/CSO

HFD/Rev.Chemist/J. Holmes

Drafted by P.F.Hughes, 08/9/95 R/D initialed by P. Cooney, 08/9/95

Review to HFD-550 Office of New Drug Chemistry Microbiology Staff Microbiology Review of Amendment #2

July 30, 1996

NDA 20-600

Applicant:

Allergan, Inc.

P.O. Box 19534

2525 Dupont Drive

Irvine, CA 92713-9534 USA

Product Names: Tazarotene

AGN 190168

Dosage Form and Route of Administration:

Topical gel packaged in collapsible aluminum tubes, 10 gram,

30 gram and 100 gram sizes containing either 0.1% or 0.05%

Tazarotene gel.

Pharmacological category:

Topical treatment of plaque psoriasis and acne.

Date of Initial Submission:

June 16, 1995

Amendment #1:

June 28, 1995

Amendment # 2:

July 3, 1996 (subject of this review).

Assigned for Review:

July 15, 1996

Remarks:

The subject of this review, Amendment dated July 3, 1996, contains responses to deficiencies

found in the original NDA submission and in the Amendment dated June 28, 1996.

Conclusions:

The amendment to NDA 20-600 for Tazarotene is recommended for approval from the

standpoint of microbiological quality of the drug product.

Patricia F. Hughes, Ph.D.

Reviewing Microbiologist

PAC 7/30/96

cc:

Original NDA 20-600 HFD-160/Consult File HFD-160/PFHughes HFD-540/Division File HFD-540/FCross

Drafted by P.F. Hughes/07/30/96 R/D initialed by P.H.Cooney/07309/96